

REMARKS

Claims 1-46 are pending in this application. All of the pending claims have been rejected under 35 U.S.C. §102(a) as anticipated by US Patent Application Publication 2002/0098159 by Wei et al. The examiner asserted that Wei et al. disclose a topically applied antimicrobial composition comprising zinc ions, ammonium ions and chloride ions which further can comprise hydrochloric acid and an aqueous carrier. This rejection is traversed.

The application by Wei et al. is directed to an antimicrobial composition comprising a proton donating agent and a surfactant. The proton donating agent can comprise an organic acid, mineral acid or mixture which results in undissociated acid on the skin after use. This broad definition encompasses hydrochloric acid, although this acid is not specifically disclosed. The surfactant can be anionic, cationic, amphoteric or zwitterionic or a combination thereof. If a cationic surfactant is used, it can be any of a wide number of quaternary ammonium salts. The composition further can comprise a range of optional components, including an aqueous component and any of a wide variety of active antimicrobial agents, including over 150 non-cationic antimicrobial agents, over 50 "natural" antimicrobial agents and more than 25 antibacterial metal salts. The most preferred antimicrobial active is said to be benzalkonium chloride. The reference further provides that the compositions can comprise a "mildness enhancer," a hydrocarbon oil or wax, a silicone oil, a di- or tri-glycerides, and/or a degreasing and/or detackifying agent.

This disclosure does not anticipate the compositions and methods of the present invention. Claim 1 has been amended above to claim a composition which consists essentially of a solution of zinc ions, ammonium ions, chloride ions and, optionally, an excipient or carrier. The claim further has been amended to specify that the zinc ions are provided in an amount sufficient to promote re-epithelialization. Support for this amendment can be found, for example, in the paragraph bridging pages 1 and 2 and the paragraph bridging pages 6 and 7 of the specification. These paragraphs explain that matrix metalloproteinases (MMPs) are involved in re-epithelialization of skin wounds; they have a catalytic domain which includes a zinc ion binding site and are important regulators of skin tissue remodeling, including re-epithelialization, through the regulation of skin cell migration, and that the zinc ions in the compositions of the invention promote the activity of MMPs to initiate the healing of skin.

The reference by Wei et al. does not teach or suggest a composition consisting essentially of a solution of zinc, ammonium ions and chloride ions, as required by claim 1 and the claims dependent therefrom. To even arrive at a composition comprising these components, based on the teachings of Wei et al., one would have to pick and choose from among an enormous selection of possible components, with no guidance to do so; there certainly is no teaching by Wei et al. to lead one to include these particular ions in a composition, and there certainly is no teaching or suggestion to prepare a composition which consists essentially of a solution of these particular ions, optionally with an excipient or carrier. Wei et al. also do not teach a composition in which zinc ions are provided in an amount sufficient to promote re-epithelialization. The reference

by Wei et al. thus does not teach, or even suggest, the composition of claim 1 or the claims dependent upon it. The compositions of Wei et al. do not promote the re-epithelialization of skin. The reference thus also does not anticipate claims 25 and 26, which are directed to a method for treating skin disorders through the administration of the composition of claim 1.

Neither does the reference anticipate independent claim 3 and the claims dependent from it. Claim 3 is directed to a composition consisting of a solution of zinc ammonium chloride, ammonium chloride, hydrochloric acid and an optional excipient or carrier. The reference does not disclose a composition consisting of such components. There is no specific disclosure anywhere in the Wei et al. reference of zinc ammonium chloride or of ammonium chloride as specific components for a composition; there certainly is no disclosure of a composition consisting of a solution of zinc ammonium chloride, ammonium chloride and hydrochloric acid. The reference thus also does not disclose a method of treating skin disorders through the administration of such a composition, as claimed in claims 43 and 45.

Similarly, the reference does not anticipate the composition of independent claim 10 and the claims dependent from it. Claim 10 is directed to a composition consisting of a solution of zinc chloride, ammonium chloride and hydrochloric acid and an optional excipient or carrier. The reference does not disclose such a composition. It thus also does not disclose a method of treating skin disorders through the administration of such a composition as set forth in claims 44 and 46.

A further note is warranted regarding the method of treatment claims. The examiner asserted that the Wei et al.

reference discloses a method of treating the skin for the disorders of the claimed group of skin disorders. Applicants respectfully submit that the examiner has mis-read the reference in this regard. The reference focuses on compositions and methods for the cleansing and disinfecting of skin. It does not teach administering a composition which will treat a skin disorder by promoting the re-epithelialization of skin. Further, it teaches away from the use of the compositions to treat disorders such as skin cancer, eczema and psoriasis. Paragraph 379 of the reference, which was cited by the examiner, provides that potential subjects having any of these conditions were excluded from the study described.

Applicants respectfully submit that in view of the foregoing amendments and discussion the pending claims are in condition for allowance.

| | | | | | |
|---|---|-----------|--------------|----------|-------------------|
| <input checked="" type="checkbox"/> Customer Number or Bar Code Label 6449 | | | | | |
| Name | Barbara G. Ernst, Reg. No. 30,377 | | | | |
| Signature | /Barbara G. Ernst / | | | Date | November 13, 2007 |
| Address | Rothwell, Figg, Ernst & Manbeck Suite 800, 1425 K Street, N.W. | | | | |
| City | Washington | State | D.C. | Zip Code | 20005 |
| Country | U.S.A. | Telephone | 202-783-6040 | Fax | 202-783-6031 |